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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,638	10/03/2001	Rachel Meyers	381552003900	1362

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Intellectual Property Group  
Millennium Pharmaceuticals Inc  
75 Sidney Street  
Cambridge, MA 02139

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/970,638

Applicant(s)

MEYERS, RACHEL

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 6, 8 in part, drawn to nucleic acid, cell, method of producing protein, kit, classified in class 536, subclass 23.1, and others. If applicant elects group I, claim 8 will be examined as drawn to nucleic acid.
  - II. Claim 4, drawn to protein, classified in class 530, subclass 350.
  - III. Claims 5, 8 in part drawn to antibody and kit, classified in class 530, subclass 387.1. If applicant elects group III, claim 8 will be examined as drawn to antibody.
  - IV. Claim 7, drawn to method of detecting the nucleic acid of group I above, classified in class 435, subclass 6.
  - V. Claim 7, drawn to method of detecting the protein of group II above, classified in class 435, subclass 7.1.
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- VI. Claim 9, 17, drawn to method of identifying a compound binding to or modulate activity of protein of group II above, classified in class 435, subclass 4.
  - VII. Claims 10, drawn to method of modulating the activity of group II protein above with yet to be identified compound, unclassifiable due to unknown structure of the compound.

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- VIII. Claims 11, 12, 14, and 15, drawn to method of identifying nucleic acid associated with a disorder using the nucleic acid of group I above, classified in class 435, subclass 6.
- IX. Claims 13, and 16, drawn to method of identifying protein associated with a disorder using the antibody of group III above, classified in class 435, subclass 7.1.
- X. Claim 17, drawn to method of identifying compounds that modulate the nucleic acid of group I above using the group I nucleic acid above, classified in class 435, subclass 6.

Claims 18 link(s) inventions 11-81 (Roman numerals become too cumbersome for these many numbers). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

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Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

11. Claim 19, 23, drawn to method of treating cancer using a small molecule, unclassifiable due to unknown nature of the small molecule.
  12. Claim 19, 23, drawn to method of treating cancer using a peptide, class 512, subclass 2.
  13. Claim 19, 23, drawn to method of treating cancer using a phosphopeptide, class 512, subclass 7.
  14. Claim 19, 23, drawn to method of treating cancer using an antibody of group III above, class 512, subclass 7.
  15. Claim 19, 23, drawn to method of treating cancer using a protein of group II above, class 512, subclass 2.
  16. Claim 19, 23, drawn to method of treating aberrant cellular proliferation and/or differentiation disorder using a small molecule, unclassifiable due to unknown nature of the small molecule.
  17. Claim 19, 23, drawn to method of treating aberrant cellular proliferation and/or differentiation disorder using a peptide, class 512, subclass 2.
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18. Claim 19, 23, drawn to method of treating aberrant cellular proliferation and/or differentiation disorder using a phosphopeptide, class 512, subclass 7.
  19. Claim 19, 23, drawn to method of treating aberrant cellular proliferation and/or differentiation disorder using an antibody of group III above, class 512, subclass 7.

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20. Claim 19, 23, drawn to method of treating aberrant cellular proliferation and/or differentiation disorder using a protein of group II above, class 512, subclass 2.
21. Claim 19, 23, drawn to method of treating hormonal disorders using a small molecule, unclassifiable due to unknown nature of the small molecule.
22. Claim 19, 23, drawn to method of treating hormonal disorders using a peptide, class 512, subclass 2.
23. Claim 19, 23, drawn to method of treating hormonal disorders using a phosphopeptide, class 512, subclass 7.
24. Claim 19, 23, drawn to method of treating hormonal disorders using an antibody of group III above, class 512, subclass 7.
25. Claim 19, 23, drawn to method of treating hormonal disorders using a protein of group II above, class 512, subclass 2.
26. Claim 19, 23, drawn to method of treating immune disorders using a small molecule, unclassifiable due to unknown nature of the small molecule.
27. Claim 19, 23, drawn to method of treating immune disorders using a peptide, class 512, subclass 2.
28. Claim 19, 23, drawn to method of treating immune disorders using a phosphopeptide, class 512, subclass 7.
29. Claim 19, 23, drawn to method of treating immune disorders using an antibody of group III above, class 512, subclass 7.

30. Claim 19, 23, drawn to method of treating immune disorders using a protein of group II above, class 512, subclass 2.
31. Claim 19, 23, drawn to method of treating brain disorders using a small molecule, unclassifiable due to unknown nature of the small molecule.
32. Claim 19, 23, drawn to method of treating brain disorders using a peptide, class 512, subclass 2.
33. Claim 19, 23, drawn to method of treating brain disorders using a phosphopeptide, class 512, subclass 7.
34. Claim 19, 23, drawn to method of treating brain disorders using an antibody of group III above, class 512, subclass 7.
35. Claim 19, 23, drawn to method of treating brain disorders using a protein of group II above, class 512, subclass 2.
36. Claim 19, 23, drawn to method of treating heart disorders using a small molecule, unclassifiable due to unknown nature of the small molecule.
37. Claim 19, 23, drawn to method of treating heart disorders using a peptide, class 512, subclass 2.
38. Claim 19, 23, drawn to method of treating heart disorders using a phosphopeptide, class 512, subclass 7.
39. Claim 19, 23, drawn to method of treating heart disorders using an antibody of group III above, class 512, subclass 7.
40. Claim 19, 23, drawn to method of treating heart disorders using a protein of group II above, class 512, subclass 2.

41. Claim 19, 23, drawn to method of treating pain disorders using a small molecule, unclassifiable due to unknown nature of the small molecule.
  42. Claim 19, 23, drawn to method of treating pain disorders using a peptide, class 512, subclass 2.
  43. Claim 19, 23, drawn to method of treating pain disorders using a phosphopeptide, class 512, subclass 7.
  44. Claim 19, 23, drawn to method of treating pain disorders using an antibody of group III above, class 512, subclass 7.
  45. Claim 19, 23, drawn to method of treating pain disorders using a protein of group II above, class 512, subclass 2.
  46. Claim 19, 23, drawn to method of treating metabolic disorders using a small molecule, unclassifiable due to unknown nature of the small molecule.
  47. Claim 19, 23, drawn to method of treating metabolic disorders using a peptide, class 512, subclass 2.
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48. Claim 19, 23, drawn to method of treating metabolic disorders using a phosphopeptide, class 512, subclass 7.
  49. Claim 19, 23, drawn to method of treating metabolic disorders using an antibody of group III above, class 512, subclass 7.
  50. Claim 19, 23, drawn to method of treating metabolic disorders using a protein of group II above, class 512, subclass 2.

51. Claim 20, 23, drawn to method of treating cancer using an antisense of 27419 nucleic acid, class 514, subclass 44.
52. Claim 20, 23, drawn to method of treating cancer using a ribozyme, class 514, subclass 44.
53. Claim 20, 23, drawn to method of treating cancer using a gene therapy, class 514, subclass 44.
54. Claim 20, 23, drawn to method of treating aberrant cellular proliferation and/or differentiation disorder using an antisense of 27419 nucleic acid, class 514, subclass 44.
55. Claim 20, 23, drawn to method of treating aberrant cellular proliferation and/or differentiation disorder using a ribozyme, class 514, subclass 44.
56. Claim 20, 23, drawn to method of treating aberrant cellular proliferation and/or differentiation disorder using a gene therapy, class 514, subclass 44.
57. Claim 20, 23, drawn to method of treating hormonal disorder using an antisense of 27419 nucleic acid, class 514, subclass 44.
58. Claim 20, 23, drawn to method of treating hormonal disorder using a ribozyme, class 514, subclass 44.
59. Claim 20, 23, drawn to method of treating hormonal disorder using a gene therapy, class 514, subclass 44.
60. Claim 20, 23, drawn to method of treating immune disorder using an antisense of 27419 nucleic acid, class 514, subclass 44.

61. Claim 20, 23, drawn to method of treating immune disorder using a ribozyme, class 514, subclass 44.
  62. Claim 20, 23, drawn to method of treating immune disorder using a gene therapy, class 514, subclass 44.
  63. Claim 20, 23, drawn to method of treating brain disorder using an antisense of 27419 nucleic acid, class 514, subclass 44.
  64. Claim 20, 23, drawn to method of treating brain disorder using a ribozyme, class 514, subclass 44.
  65. Claim 20, 23, drawn to method of treating brain disorder using a gene therapy, class 514, subclass 44.
  66. Claim 20, 23, drawn to method of treating brain disorder using an antisense of 27419 nucleic acid, class 514, subclass 44.
  67. Claim 20, 23, drawn to method of treating brain disorder using a ribozyme, class 514, subclass 44.
  68. Claim 20, 23, drawn to method of treating brain disorder using a gene therapy, class 514, subclass 44.
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69. Claim 20, 23, drawn to method of treating heart disorder using an antisense of 27419 nucleic acid, class 514, subclass 44.
  70. Claim 20, 23, drawn to method of treating heart disorder using a ribozyme, class 514, subclass 44.
  71. Claim 20, 23, drawn to method of treating heart disorder using a gene therapy, class 514, subclass 44.

- 72. Claim 20, 23, drawn to method of treating pain disorder using an antisense of 27419 nucleic acid, class 514, subclass 44.
  - 77. Claim 20, 23, drawn to method of treating pain disorder using a ribozyme, class 514, subclass 44.
  - 78. Claim 20, 23, drawn to method of treating pain disorder using a gene therapy, class 514, subclass 44.
  - 79. Claim 20, 23, drawn to method of treating metabolic disorder using an antisense of 27419 nucleic acid, class 514, subclass 44.
  - 80. Claim 20, 23, drawn to method of treating metabolic disorder using a ribozyme, class 514, subclass 44.
  - 81. Claim 20, 23, drawn to method of treating metabolic disorder using a gene therapy, class 514, subclass 44.
  - 82. Claim 21, drawn to method of evaluating efficacy of treatment by detecting expression of the group I nucleic acid above, classified in class 435, subclass 6.
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- 83. Claim 21, drawn to method of evaluating efficacy of treatment by detecting expression of the group II protein above, classified in class 435, subclass 7.1.
  - 84. Claim 22, drawn to method of diagnosing a disorder by detecting expression of the group I nucleic acid above, classified in class 435, subclass 6.

85. Claim 22, drawn to method of diagnosing a disorder by detecting expression of the group II protein above, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and (IV, VIII, X, 82, 84) are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using group IV, VIII, X, 82, or 84.

Inventions II and (VI, VII, IX, 83, 85) are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using group VI, VII, IX, 83 or 85.

Inventions III and (V, 14) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using group V, and 14.

Inventions 11-81 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation (uses different active ingredients) or different effects (treating different diseases).

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642

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LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER